



# D STATES DEPARTMENT OF COMMERCE

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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.	
09/523,760	03/07/00	TANEJA		K	BP9806US-CP1	
Г 023544		HM12/0921	¬ [	EXAMINER		
BRIAN D. GILDEA BOSTON PROSES, INC.				SQUAYS ART UNIT	PAPER NUMBER	
15 DIANGEL BEDFORD MA				1655 DATE MAILED:	7	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

09/21/01

## Application No.

09/520,760

Applicant(s)

Examiner

Art Unit 1655

Taneja



### Office Action Summary

Jehanne Souaya

The MAILING DATE of this communication appears on the o	over sheet with the correspondence address
Period for Reply	DIDE 4 MONTH/C\ EDOM
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXITHE MAILING DATE OF THIS COMMUNICATION.	
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 after SIX (6) MONTHS from the mailing date of this communication.</li> </ul>	
- If the period for reply specified above is less than thirty (30) days, a reply be considered timely.	
<ul> <li>If NO period for reply is specified above, the maximum statutory period w communication.</li> </ul>	
<ul> <li>Failure to reply within the set or extended period for reply will, by statute,</li> <li>Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	cause the application to become ABANDONED (35 U.S.C. § 133). date of this communication, even if timely filed, may reduce any
Status	
1) 💢 Responsive to communication(s) filed on Mar 7, 2000	•
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This action is n	
3) Since this application is in condition for allowance except closed in accordance with the practice under Ex parte Que	for formal matters, prosecution as to the merits is ayle, 1935 C.D. 11; 453 O.G. 213.
Disposition of Claims	
4) X Claim(s) 1, 2, 10-12, 29, 31, 33, 34, 39, 40, 45, 47, 49,	. 50, 54-56, 64-66, is/are pending in the application.
4a) Of the above, claim(s)	is/are withdrawn from consideration.
5) Claim(s)	
6) Claim(s)	
7) Claim(s)	
8) X Claims 1, 2, 10-12, 29, 31, 33, 34, 39, 40, 45, 47, 49,	50, are subject to restriction and/or election requirement.
Application Papers	
9) The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/are object	ted to by the Examiner.
11) The proposed drawing correction filed on	is: a) $\square$ approved b) $\square$ disapproved.
12) $\square$ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
13) Acknowledgement is made of a claim for foreign priority	under 35 U.S.C. § 119(a)-(d).
a) $\square$ All b) $\square$ Some* c) $\square$ None of:	
<ol> <li>Certified copies of the priority documents have been</li> </ol>	
	received in Application No
3. Copies of the certified copies of the priority docume application from the International Bureau (PC	,1 Hule 17.2(a)).
*See the attached detailed Office action for a list of the certification	
14) Acknowledgement is made of a claim for domestic priori	ty under 55 5.5.5. 3 1 15(5).
Attachment(s)	
15) Notice of Materialices cited (110 002)	Interview Summery (PTO-413) Paper No(s).
16) X Notice of Chartspoison 5 / Atom Commission	Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20)	Other:

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#### **DETAILED ACTION**

#### Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to nucleic acid probes directed to human chromosome X and to methods and kits for detecting, identifying, or quantitating human chromosome X in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
  - II. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome Y and to methods and kits for detecting, identifying, or quantitating human chromosome Y in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
  - III. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 1 and to methods and kits for detecting, identifying, or quantitating human chromosome 1 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
  - IV. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 2 and to methods and kits for detecting, identifying, or quantitating human chromosome 2 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

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- V. Claims 1-2, 10-12, 29, 39-40, 45, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 3 and to methods and kits for detecting, identifying, or quantitating human chromosome 3 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- VI. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 6 and to methods and kits for detecting, identifying, or quantitating human chromosome 6 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- VII. Claims 1-2, 10-12, 31, 39-40, 47, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 8 and to methods and kits for detecting, identifying, or quantitating human chromosome 8 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- VIII. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 10 and to methods and kits for detecting, identifying, or quantitating human chromosome 10 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- IX. Claims 1-2, 10-12, 33, 39-40, 49, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 11 and to methods and kits for detecting, identifying, or quantitating human chromosome 11 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.

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- X. Claims 1-2, 10-12, 34, 39-40, 50, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 12 and to methods and kits for detecting, identifying, or quantitating human chromosome 12 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- XI. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 16 and to methods and kits for detecting, identifying, or quantitating human chromosome 16 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- XII. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 17 and to methods and kits for detecting, identifying, or quantitating human chromosome 17 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- XIII. Claims 1-2, 10-12, 39-40, 54-56, 64-66 and 78-81, drawn to drawn to nucleic acid probes directed to human chromosome 18 and to methods and kits for detecting, identifying, or quantitating human chromosome 18 in a sample, classified in class 536, subclass 23.1 and class 435, subclass 6.
- 2. The inventions are distinct, each from the other because of the following reasons: Each group is directed to nucleic acid sequences that identify or detect a different human chromosome. Each of the sequences are structurally and functionally different from each other. That is structurally, the sequences comprise a different sequences of nucleotide bases, thus resulting in

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unique sequences. Functionally, the sequences are different in that they identify or detect different chromosomes. The methods of each group are also patentably distinct because the method for detecting chromosome X is different from the method of detecting chromosome Y in that the sequences required to detect each chromosome are different. Each chromosome is made up of different nucleic acid sequences that are patentably distinct from each other and require different nucleic acid sequences for their identification or detection.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Nucleotide sequences that detect different chromosomes are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XIII, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant should also indicate the SEQ ID NOS of the probes required for identification of a single chromosome.
- 6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

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Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Patent examiner
September 18,3001

W. Gary Jones Supervisory Patent Examiner

Technology Center 1600